

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015 (GBW)
)	
SAREPTA THERAPEUTICS, INC.,)	PUBLIC VERSION
)	
Defendant.)	
<hr/>)	
SAREPTA THERAPEUTICS, INC. and THE)	Confidential Version Filed: August 9, 2023
UNIVERSITY OF WESTERN AUSTRALIA,)	Public Version Filed: August 16, 2023
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.)	
)	
Plaintiff/Counter-Defendants.)	

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS REGARDING
MOTION TO EXCLUDE DR. MATTHEW WOOD AS AN EXPERT WITNESS**

Dear Judge Williams:

Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”) should not be permitted to disclose Defendants’ Protected Material to Dr. Wood. Indeed, for the reasons set forth in Defendants’ August 3, 2023, letter brief (D.I. 298), Dr. Wood should be disqualified from serving as NS’s expert in any capacity.

NS grossly understates the scope of Dr. Wood’s relationship with Sarepta, mentioning only [REDACTED] his service as an expert witness in interference proceedings. But as detailed in Defendants’ August 3, 2023, letter brief—[REDACTED]

NS contends that Dr. Wood “is not engaged in decision-making for NS *or any other Sarepta competitor*” (D.I. 300 at 2) but neglects to mention that Dr. Wood is a co-founder and current Scientific Advisory Board member of PepGen Inc. As PepGen stated in its filing with the United States Securities and Exchange Commission in conjunction with its initial public offering in 2022, PepGen has a compound in development specifically directed to skipping of exon 53, and it considers itself a direct competitor of Sarepta:

Competition

...

We expect to face competition from existing products and product candidates in development for each of our programs. . . . [T]here are four FDA-approved exon skipping drugs: EXONDYS 51 (Eteplirsen), VYONDYS 53 (Golodirsen) and AMONDYS 45 (Casimersen), which are naked PMOs approved for the treatment of DMD patients amenable to exon 51, exon 53 and exon 45 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc. . . .

Ex. 1¹ at 156.² At the time of that initial public offering, Dr. Wood was identified in PepGen’s prospectus as a member of PepGen’s Board of Directors (*id.* at 196), and he is currently the Chair of PepGen’s Scientific Advisory Board (Ex. 2³). Indeed, Sarepta no longer works with Dr. Wood directly in light of his association with PepGen. In view of the close, ongoing relationship

¹ PepGen’s May 5, 2022, Prospectus, *available at* <https://investors.pepgen.com/static-files/23f3facf-7050-4459-ade7-bb6e67255509> (last visited Aug. 9, 2023).

² PepGen also identifies NS as a competitor. *Id.* But NS can choose not to provide Dr. Wood access to its own Protected Material, whereas granting the relief NS seeks would permit NS to share *its competitor’s* Protected Material with Dr. Wood.

³ “PepGen Announces Formation of Scientific Advisory Board,” *available at* <https://investors.pepgen.com/node/6391/pdf> (last visited Aug. 9, 2023).

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Dr. Wood has with PepGen, the company he co-founded and that is developing a therapy directly competitive with Sarepta's golodirsen product,⁴ the *Advanced Micro Devices* case relied on by NS is inapposite.

Apart from minimizing Dr. Wood's relationship with Sarepta and omitting his ongoing involvement with PepGen, NS also ignores the fact that it seeks to induce Dr. Wood to switch sides: from serving as an expert who defended the *validity* of patents in the same family as the patents asserted by Defendants here to one who will opine regarding the *invalidity* of those asserted patents. As explained in Sarepta's August 3, 2023, letter brief, NS contends that the Van Ommen reference renders the asserted claims of the UWA patents obvious. D.I. 298 at 2; D.I. 299-1, Exs. 9-10. But Dr. Wood provided opinions in three interference proceedings before the USPTO involving patents in the same family as the patents-in-suit here directed to why that reference did *not* render obvious the claims of those related patents. D.I. 298 at 2; D.I. 299-1, Ex. 11.

[REDACTED]

Further, [REDACTED]

In view of his involvement with PepGen, which expressly asserts that it competes with Sarepta, disclosure of additional Protected Material of the Defendants would result in great prejudice to Defendants. Indeed, "courts have traditionally recognized that disclosure to a competitor is more harmful than disclosure to a noncompetitor." *Mannington Mills, Inc. v. Armstrong World Indus., Inc.*, 206 F.R.D. 525, 531 (D. Del. 2002); *accord Monolithic Power Sys.*,

⁴ In addition to being a direct competitor for exon 53, PepGen also has therapies in development directed towards exons 51 and 45, which are the targets of Sarepta's other marketed exon-skipping therapies. See Ex. 3, PepGen Pipeline, available at <https://www.pepgen.com/pipeline/> (last visited Aug. 9, 2023).

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Inc. v. Intersil Corp., No. 16-1125-LPS, 2018 WL 6113465, at * 1 (D. Del. Nov. 19, 2018) (“Courts generally afford more protection to proprietary technical information than to ordinary business information due to the threat of serious economic injury resulting from disclosure to competitors.”).

The negotiated Protective Order in this matter contemplates that the parties will produce documents that contain information about sensitive products, proprietary design and development materials, strategic decision-making information, and marketing and sales information. D.I. 117 at 1. The Protective Order defines varying categories of such information depending on the degree of sensitivity of the information and the degree of risk of harm that disclosure of that information would create. *Id.* at ¶¶ 2.2, 2.7, 2.11. The Protective Order acknowledges the likely harm that would occur if certain information were disclosed to a competitor by prohibiting disclosure of Highly Confidential material to the parties’ employees (apart from specifically enumerated inside counsel) and prohibiting disclosure of Outside Counsel Eyes Only material to any party employee. Indeed, the parties have regularly designated the kind of information NS seeks to disclose to Dr. Wood as Highly Confidential—meaning it cannot be shared with employees apart from specified counsel—to guard against the risk that information would be used to competitive advantage.

Because Dr. Wood is so closely aligned with PepGen, disclosure to him of Defendants’ Protected Material would allow Dr. Wood to evaluate PepGen’s competitor’s proprietary research and development approaches, identify their strategic objectives, and obtain sensitive financial information. Even though Dr. Wood has agreed to be bound by the Protective Order, courts realize the impracticality of an expert—particularly one associated with a competitor—segregating in his mind information obtained through discovery and not using it—albeit inadvertently—in his other activities. *Monolithic*, 2018 WL 6113465, at * 1 (“There is a risk that [the expert] would conflate the knowledge he learned from confidential information disclosed to him in this case with knowledge he possesses from his consulting work in current and future dealings with [Plaintiff’s] competitors), citing *Safe Flight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F. Supp. 20, 22 (D. Del. 1988) (doubting human ability to separate applications extrapolated from party’s confidential information from those developed as one’s own ideas).

Finally, NS would not be harmed if it cannot obtain the relief it seeks. NS has already retained and identified numerous other experts that could provide the opinions it might seek from Dr. Wood, and thus NS would not be prejudiced if Dr. Wood could not serve as its expert.

For the reasons set forth in Defendants’ August 3, 2023, letter brief, Dr. Wood should be disqualified from serving as an expert in any capacity, thereby rendering moot NS’s request to disclose Protected Material to him. But in the event that Dr. Wood is permitted to serve as an expert, his prior exposure to Defendants’ confidential and privileged information and involvement with PepGen justify precluding NS from disclosing Defendants’ Protected Material to Dr. Wood.

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Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac
Attachments

cc: Clerk of the Court (via hand delivery; w/attachments)
All Counsel of Record (via electronic mail; w/attachments)